lupus erythematosus, Sjögren's syndrome, Behçet's disease, scleroderma, primary biliary cirrhosis, microscopic polyangitis/polyarteritis nodosa, ulcerative colitis, Chrohn's disease and autoimmune hepatitis.

## REMARKS

The active claims in this case are claims 4, 6-7, and 9-13.

For the Examiner's convenience, a list of currently pending claims is attached at the end of this document.

Applicants do not believe that any fees are due at this time; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to this document, the Assistant Commissioner is authorized to deduct the fees from Baker Botts, L.L.P. Deposit Account No. 02-0383.

The claim limitation of an "instruction protocol" has been removed in order to expedite prosecution of the pending claims.

As discussed in Applicant's Response dated November 28, 2000, Applicant maintains that the claimed invention is both novel and non-obvious over the cited prior art.

Ayer et al. (*Arthritis & Rheumatism* 37(1): 98-103 (1994); hereinafter "Ayer") found an increase in antibodies to HMG-14 and –17 in drug-induced lupus, but not naturally occurring disease. As Applicant showed in the previous response, HMG-14 and –17 are quite distinct from HMG-1 and –2. Ayer indicates that antibodies against HMG-1 and –2 are evenly distributed in active and non-active genes (page 102). This, combined with the low correlation of antibodies against HMG-1 and/or –2 compared to those against HMG-14 and/or –17 (21% vs. 67%) teaches away from the claimed invention.

Neuer et al. (*Arthritis and Rheumatism*, 35(4): 472-475, 1992) further stated that antibodies reactive against HMG-1 or –2 are not useful in the prediction of juvenile rheumatoid arthritis.

Accordingly, one of ordinary skill in the art would not be motivated by the cited art to use HMG-1 and HMG-2 in a kit for detecting autoimmune disease. In fact, the art would lead the skilled artisan to not select HMG-1 and HMG-2.

Respectfully submitted,

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Marked up version of rewritten claims amended in this Preliminary Amendment

4. (Twice Amended) A kit for diagnosing an autoimmune disease, the kit comprising:

a first antigen comprising a polypeptide from an HMG-1 family or a fragment of a polypeptide from the HMG-1 family;

a second antigen comprising a polypeptide from an HMG-2 family or a fragment of a polypeptide from the HMG-2 family;

a first component for detecting a first antigen-antibody complex; and

a second component for detecting a second antigen-antibody complex; [and

an instruction protocol for correlating the detection of either or both of the first antigen-antibody complex and the second antigen-antibody complex with the autoimmune disease,] wherein the autoimmune disease is selected from the group consisting of human systemic lupus erythematosus, Sjögren's syndrome, Behçet's disease, scleroderma, primary biliary cirrhosis, microscopic polyangitis/polyarteritis nodosa, ulcerative colitis, Chrohn's disease and autoimmune hepatitis.

Currently pending claims for U.S. Patent Application Serial No. 09/214,881

4. (Twice Amended) A kit for diagnosing an autoimmune disease, the kit comprising:

a first antigen comprising a polypeptide from an HMG-1 family or a fragment of a polypeptide from the HMG-1 family;

a second antigen comprising a polypeptide from an HMG-2 family or a fragment of a polypeptide from the HMG-2 family;

a first component for detecting a first antigen-antibody complex; and

a second component for detecting a second antigen-antibody complex; wherein the autoimmune disease is selected from the group consisting of human systemic lupus erythematosus, Sjögren's syndrome, Behçet's disease, scleroderma, primary biliary cirrhosis, microscopic polyangitis/polyarteritis nodosa, ulcerative colitis, Chrohn's disease and autoimmune hepatitis.

6. (Amended) The kit of claim 4, wherein:

the polypeptide from an HMG-1 family is selected from human, bovine, porcine, chicken, mouse, or rat HMG-1; and

the polypeptide from an HMG-2 family is selected from human, bovine, porcine, chicken, mouse, or rat HMG-2.

7. (Amended) A method for diagnosing an autoimmune disease in a patient, the method comprising the step of detecting one or more antibodies in the patient by contacting a reagent with antibodies from the patient, the reagent comprising at least one polypeptide selected from the group consisting of a polypeptide from an HMG-1 family, a polypeptide from an HMG-2 family, and a fragment of a polypeptide from the HMG-1 family or the HMG-2 family, wherein

the at least one polypeptide reacts with an antibody of an autoimmune disease patient, and

the autoimmune disease is selected from the group consisting of human systemic lupus erythematosus, Sjögren's syndrome, Behçet's disease, scleroderma, primary biliary cirrhosis, microscopic polyangitis/polyarteritis nodosa, ulcerative colitis, Chrohn's disease and autoimmune hepatitis.

9. (Amended) The method of claim 7, wherein:

the polypeptide from an HMG-1 family is human, bovine, porcine, chicken, mouse, or rat HMG-1; and

the polypeptide from an HMG-2 family is human, bovine, porcine, chicken, mouse, or rat HMG-2.

10. (Added) A method of diagnosing an autoimmune disease in a patient, the method comprising:

detecting the presence or absence in the patient of antibodies to HMG-1, HMG-2, or both HMG-1 and HMG-2; and

diagnosing the autoimmune disease based on the antibodies detected, wherein the autoimmune disease is selected from the group consisting of human systemic lupus erythematosus, Sjögren's syndrome, Behçet's disease, scleroderma, primary biliary cirrhosis, microscopic polyangitis/polyarteritis nodosa, ulcerative colitis, Chrohn's disease, and autoimmune hepatitis.

11. (Added) A method of diagnosing the cause or prognosis of an ulcerative colitis patient, the method comprising contacting antibodies isolated from the patient with a polypeptide selected from an HMG-2 family, or an effective fragment thereof, wherein the polypeptide or fragment reacts with an antibody to HMG-2.

12. (Added) The method of claim 11, further comprising contacting antibodies from the patient with a polypeptide selected from an HMG-1 family, or an effective fragment thereof, wherein the polypeptide or fragment reacts with an antibody to HMG-1.

13. (Added) The method of claim 11, further comprising determining whether the patient is ANCA-negative or ANCA-positive.